

REMARKS

In the Office Action dated September 29, 2010, claims 1-37 and 39-48 were pending, of which claims 1-35, 37, and 40-45 were withdrawn and claims 36, 39, and 46-48 were rejected.

The Examiner has rejected claim 39 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner has also rejected claims 36, 39, and 46-48 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Further, the Examiner has rejected claims 36 and 48 under 35 U.S.C. § 112, first paragraph, as allegedly introducing new matter and failing to comply with the written description requirement. The Examiner has additionally rejected claims 36 and 48 under 35 U.S.C. § 102(a) as allegedly anticipated by Coombs et al. (*Plasmid*, 2003). The Examiner has also rejected claims 36 and 46-48 under 35 U.S.C. § 102(a) as allegedly anticipated by Coombs (Thesis).

This Response addresses the Examiner's rejections. Accordingly, favorable consideration of the claims as presented herein is respectfully requested.

Amendments to the Claims

To favorably advance prosecution, and without prejudice or disclaimer, Applicants have amended the claims to delete the subject matter drawn to non-elected groups and non-elected species. Applicants reserve the rights to pursue the non-elected subject matter in this application or a subsequent continuing application. The remaining claims, claims 36, 39, and 46-48, are drawn to an isolated endophytic actinomycete characterized by a nucleotide sequence which hybridizes or has greater than 98% or 99% identity to SEQ ID NO: 7, and to an antibody directed to such endophytic actinomycete.

Applicants have also amended claim 36, without prejudice or disclaimer, to delete the

phrase "substantially". In addition, Applicants have amended claim 48 to present an acceptable multiple dependent claim wording. See M.P.E.P. § 608.01(n).

No new matter is introduced by the foregoing amendments.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph—Written Description

The Examiner has rejected claim 39 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner has asserted that the specification of the subject application does not disclose a single example of a proteinaceous or non-proteinaceous molecule that would be a metabolite for SEQ ID NO: 7 or an antibody against SEQ ID NO: 7.

In response, Applicants respectfully traverse. Applicants respectfully submit that claim 39 complies with the written description requirement for at least the reasons that follow.

As an initial matter, Applicants respectfully submit that the Examiner's remarks regarding "metabolites" are inapplicable to claim 39, as presented herein. Specifically, Applicants note that claim 39 is drawn to antibodies and does not recite the language "metabolite" or "metabolites".

With respect to antibodies, the Examiner has contended that the antibodies of claim 39 have not been actually reduced to practice. The Examiner has further asserted that the specification of the subject application does not disclose any relevant identifying characteristics in the way of complete or partial structure. The Examiner has concluded that that Applicants "have not provided any evidence that they were in possession [of the claimed] antibodies".

Applicants respectfully submit that the law does not require a reduction to practice for the purpose of satisfying the written description requirement under 35 U.S.C. §112, first

paragraph. According to section 2163.I of the *Manual of Patent Examining Procedure*, possession of the invention may be shown by actual reduction to practice, or by describing the invention with sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, physical and/or chemical properties, correlation between structure and function, or some combination thereof. In the present case, the identifying characteristics of the claimed antibodies are their specificity to the unique endophytic actinomycete characterized by a nucleotide sequence which hybridizes or has greater than 98% or 99% identity to SEQ ID NO: 7. Once such endophytic actinomycete is provided by this invention, those skilled in the art would readily make and envision antibodies directed to such endophytic actinomycete. This is similar to cases where when a novel protein has been isolated, actual production of an antibody to the novel protein would not be required in order to claim the antibody to such protein.

Therefore, Applicants respectfully submit that claim 39 complies with the written description requirement under 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph—Definiteness

The Examiner has rejected claims 36, 39, and 46-48 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Specifically, the Examiner has asserted that the language "the nucleotide sequence substantially as set forth in SEQ ID NO: . . ." is unclear because it is not clear as to what "substantial correspondence" refers.

In response, without conceding the propriety of the Examiner's position, Applicants have herein amended claim 36, from which claims 39 and 46-48 depend. Applicants respectfully submit that claims 36, 39, and 46-48, as presented herein, are not indefinite under 35 U.S.C.

§ 112, second paragraph. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph—New Matter

The Examiner has rejected claims 36 and 48 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner has concluded that the amendment of claims 36 and 48 to recite the language "high stringency conditions at 42 °C" introduced new matter.

The Examiner has asserted that, while the specification mentions high stringency, it never states that these conditions are utilized to obtain "nucleotide sequence capable of hybridizing to SEQ ID NO 7". The Examiner has asserted that whenever SEQ ID NO: 7 is mentioned, only low stringency conditions are outlined. The Examiner has contended that, based on the emphasis on low stringency conditions taught throughout the specification, one could not conclude that the specification also discloses hybridization under high stringency conditions for SEQ ID NO: 7.

In response, Applicants respectfully traverse.

Applicants respectfully maintain that the specification of the subject application as originally filed discloses "high stringency conditions at 42°C". Specifically, Applicants note that page 51, line 27, to page 52, line 7, of the specification discloses as follows:

Reference herein to a low stringency includes and encompasses from at least about 0% v/v to at least about 15% v/v formamide and from at least about 1M to at least about 2M salt for hybridisation, and at least about 1M to at least about 2M salt for washing conditions. Alternative stringency conditions may be applied where necessary, such as medium stringency, which includes and encompasses from at least about 16% v/v to at least about 30% v/v formamide and from at least about 0.5M to at least about 0.9M salt

for hybridisation, and at least about 0.5M to at least about 0.9M salt for washing conditions, or high stringency, which includes and encompasses from at least about 31% v/v to at least about 50% v/v formamide and from at least about 0.01M to at least about 0.15M salt for hybridisation, and at least about 0.01M to at least about 0.15M salt for washing conditions. Stringency may be measured using a range of temperature such as from about 40EC to about 65EC. Particularly useful stringency conditions are at 42EC.

Applicants respectfully submit that both "low stringency" and "high stringency" conditions are clearly disclosed in the above-cited passage of the specification. Those skilled in the art clearly would understand that this description is applicable to all the nucleic acids described in the application. It seems that the Examiner is interpreting the written description requirement as requiring a literal recitation of each type of stringency conditions for each of the many nucleic acid molecules identified in the application. That would be impractical and should not be necessary.

Applicants respectfully submit that the law does not require that the claimed subject matter be described in the specification *ipsis verbis* in order to satisfy the written description requirement. Rather, the relevant inquiry is whether the application has conveyed with *reasonable* clarity to *those skilled in the art* that the inventors had possession of the claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).

In the present case, considering the entirety of the instant disclosure and the above-cited passage, Applicants respectfully submit that the specification has conveyed to those skilled in the art, with reasonably clarity, that Applicants are in possession of a nucleic acid capable of hybridizing to SEQ ID NO: 7 under high stringency conditions at 42°C, as presently claimed. Accordingly, Applicants respectfully submit that claims 36 and 48, as presented herein, comply with the written description requirement under 35 U.S.C. § 112, first paragraph. Applicants

therefore respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections Under 35 U.S.C. § 102(a)—Coombs et al. (2003)

The Examiner has rejected claims 36 and 48 under 35 U.S.C. § 102(a) as allegedly anticipated by Coombs et al., 49 Plasmid 86 (2003). Specifically, the Examiner has asserted that Coombs et al. "teaches pEN2701 which reads on the sequence claim 36, SEQ ID NO 12".

In response, Applicants respectfully submit that claims 36 and 48, as amended, do not recite SEQ ID NO: 12. Based on a Blast comparison, a portion of SEQ ID NO: 12 shares approximately 95% identity with a portion of SEQ ID NO: 7 (i.e., best local identity). Therefore, there is no evidence of record, or at least the Examiner has not established, that SEQ ID NO: 12 would be a nucleotide sequence that would meet the sequence characteristics recited in claims 36 and 48.

Applicants further respectfully submit that the Coombs et al. reference is a publication from the inventors' own group. Applicants therefore reserve the rights to obviate the reference by a Katz Declaration if necessary.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections Under 35 U.S.C. § 102(a)—Coombs (Thesis)

The Examiner has rejected claims 36 and 46-48 under 35 U.S.C. § 102(a) as allegedly anticipated by Coombs, Ph.D. thesis, Flinders University. Specifically, the Examiner has asserted that the thesis teaches all of the endophytic actinomycetes claimed herein. Additionally, the Examiner has asserted that the thesis "teaches the sequence corresponding to pEN27 which

reads on the sequence claim 36, SEQ ID NO 12". On page 3 of the Office Action, the Examiner stated that absent evidence to the contrary, the thesis is considered to have been publically available in 2001, the date allegedly identified by a search on the Flinder University Library system.

In response, Applicants respectfully traverse. Specifically, Applicants respectfully submit that the Coombs thesis is not a "printed publication" under 35 U.S.C. §§ 102(a)-(b) because the evidence of accessibility of Coombs is insufficient to raise a presumption that the thesis was available to the public prior to the priority date of the present application (July 2003).

With respect to the Coombs thesis, Applicants hereby submit further information regarding the submission of Coombs to the library system of Flinders University, the embargo to which the thesis was subject, and the extremely limited information on the thesis that the library system of Flinders University made available during the embargo.

In accordance with the practice of Flinders University, all potential thesis examiners were required to sign a confidentiality agreement before receiving a doctoral thesis for examination. Furthermore, the Coombs thesis was subject to an embargo until December 3, 2004, i.e. after the earliest claimed filing date of the subject application. During the embargo, readers other than academics and research students of Flinders University were not permitted to read Coombs without signing and acknowledging that they would not publish any part thereof. Additionally, only the title and author details of Coombs was available on the library system of Flinders University during the embargo period; no abstract for Coombs or any further details were available.

Applicants note that section 2128.01(I) of the current *Manual of Patent Examining Procedure* provides that "[e]ven if access to the library is restricted, a reference will constitute a

'printed publication' as long as a presumption is raised that the portion of the public concerned with the art would know of the invention", citing In re Bayer, 196 U.S.P.Q. 670 (C.C.P.A. 1978).

For the Examiner's convenience, Applicants enclose a copy of Bayer and set forth below a brief summary of the case below.

During a period of processing within a university library, the only way an interested party could identify the thesis at issue in Bayer was by author name, thesis title, or a description of the subject matter disclosed in the thesis. Id. at 672. However, the thesis examiners had access to the thesis at issue and there was no indication that the examiners were subject to a continued obligation of confidentiality. Id. at 673. At issue in Bayer was whether, under these circumstances, an "uncatalogued, unshelved thesis, by virtue of its accessibility to the graduate committee, is a 'publication' within the meaning of 35 USC 102(b)". Id. Reversing a decision of the United States Patent and Trademark Office's Board of Patent Appeals, the Court held that the thesis was not a publication. Id. at 674-75.

In Bayer, the Court held that "a printed document may qualify as a 'publication' under 35 USC 102(b), notwithstanding that accessibility thereto is restricted to a 'part of the public,' so long as accessibility is sufficient 'to raise a presumption that the public concerned with the art would know of [the invention].'" Id. at 674 (alteration in original). The Court held that accessibility of the thesis by the examiners of the thesis at issue did not raise such a presumption even in the absence of an obligation of confidentiality. See id. at 673-74. The Court also held that "since appellant's thesis could have been located in the university library only by one having been informed of its existence by the faculty committee, and not by means of the customary research aids available in the library, the 'probability of public knowledge of the contents of the [thesis],' was virtually nil". Id. at 674 (underlining added; alteration in original; internal citation

omitted). Therefore, the Court reversed the Board's decision. Id. at 675.

Applicants respectfully submit that, like the graduate committee in Bayer, accessibility of the Coombs thesis by the thesis examiners is insufficient to raise a presumption that the public concerned with the art would know of the claimed subject matter. Furthermore, whereas there was no indication in Bayer that the graduate committee was subject to a continued obligation of confidentiality, the examiners of the Coombs thesis were subject to such an agreement.

Applicants further respectfully submit that, like the information available prior to completion of processing of the thesis at issue in Bayer, the information available during the embargo is insufficient to raise a presumption that the public concerned with the art would know of the claimed subject matter. Id. Specifically, in Bayer, the Court held that, prior to completion of the processing, "one would have had to identify the thesis by author or title, or describe the subject matter thereof with particularity". Id. at 672. The Court in Bayer held that "the 'probability of public knowledge of the contents of the [thesis] was virtually nil". Id. at 674 (underlining added; alteration in original; internal citation omitted). Applicants note that the information available during the embargo of the Coombs thesis, namely the author's name and the title of the thesis without an abstract, was even less than that available in Bayer.

Therefore, neither the accessibility of the examiners of Coombs, nor the information available on the Coombs thesis during the embargo period, is sufficient to raise a presumption that the public concerned with the art would know of the subject matter of claims 36 and 46-48.

Moreover, even assuming, *arguendo*, that the thesis was publically available prior to the priority date of the present application, there is no evidence of record that the isolated endophytic actinomycete (EN16) characterized by SEQ ID NO: 7 itself was publically available.

The reference to EN16 in the Coombs thesis, without more, could simply be arbitrary laboratory designation. Absent sequence information or publically available deposit of the EN16 isolate, it is Applicants' position that the endophytic actinomycete was not made publically available simply on the basis of the publication of the thesis.

Therefore, Applicants respectfully submit that the rejection of claims 36 and 46-48 under 35 U.S.C. § 102(a) as anticipated by the Coombs thesis is improper. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'XZ' followed by a long horizontal stroke.

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